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EXAMINER	
WELLS, LAUREN Q	
ART UNIT	**PAPER NUMBER**
1617	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/031,581	Applicant(s) HASHMI ET AL.	
	Examiner Lauren Q Wells	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 22-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 22-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-19 and 22-34 are pending. The Amendment filed 5/5/03, Paper No. 5, amended claims 1 and 2.

Applicant's amendments to claims 1 and 2 are sufficient to overcome the Lack of Unity Requirement in the Previous Office Action.

Specification

(i) The use of the trademarks Enzogenol and Pycnogenol have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

(ii) The disclosure is objected to because of the following informalities: Page 24 of the specification is in a language other than English. A translation of this page is required.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating inflammation, degenerative joint complaints, cartilaginous degeneration, gastrointestinal sensitivity or irritation, does not reasonably provide enablement for

treating cancerous tumors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention is directed toward treating inflammation, degenerative joint complaints, cartilaginous degeneration, gastrointestinal sensitivity or irritation, and cancerous tumors with a composition comprising a green-lipped mussel extract and/or shark cartilage.

(2) The state of the prior art

The prior art teaches that it is know to treat inflammation, degenerative joint complaints, cartilaginous degeneration, gastrointestinal sensitivity or irritation with a composition comprising green-lipped mussel extract or shark cartilage. See US 4,801,453; 6,255,295; 6,028,118; GB 2347349 for examples of such prior art. However, the prior art is silent about treating cancerous tumors with such a composition.

Furthermore, cancer is neither a simple disease, nor a single disease. While some cancers can be treated in some hosts using specific compounds, the effective treatment of various forms of cancer and the use of structurally related compounds remains an unpredicatable art. The data present in the instant specification is not sufficient to support the scope of the present claims. In re Hozumi, 226 USPQ 353 (Comr. Dec. 1985); MPEP 706.03(n) and 706,03(z).

(3) The relative skill of those in the art

The relative skill of the those in the art is high, as cancer and its disease pathways are complex.

(4) The predictability or unpredictability of the art

The unpredictability in the cancer treatment art is very high. As pointed out above, cancer is not a single disease, but comprises an incredible number of diseases comprised of an incredible number of cell types and mechanistic pathways. Thus, a compound that may work to treat one type of cancer cell, may have no effect or even a detrimental effect on another type of cancer cell.

(5) The breadth of the claims

The claim is very broad. The instant claim is directed toward treating a number of different, and unrelated disorders, by administering a single compound. The disorders encompassed by the instant claim is anything that affects the GI tract, anything that causes inflammation, and anything that degenerates joints and cartilage, and any cancer.

(6) The amount of direction or guidance presented

The specification provides direction and guidance as to how to treat GI sensitivities, inflammatory and joint disorders, through its written description and examples. However, the specification provides no guidance or direction as to how to treat one cancerous tumor, let alone, all cancerous tumors. The specification merely recites that the instant compositions treats cancerous tumors.

(7) The presence or absence of working examples

The only working examples in the present invention are directed toward methods of treating inflammatory and joint disorders. The specification provides no examples for treating cancerous tumors.

(8) The quantity of experimentation necessary

Since the significance of particular cancerous tumors for different aspects of biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine what compositions of green-lipped mussel extract and shark cartilage would be effective.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19, 22-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claims 5-7 contain the trademarks/trade names Enzogenol and Pycnogenol. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the

goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe bark extracts and antioxidants and, accordingly, the identification/description is indefinite.

(ii) Claim 5 recites the limitation "wherein said anti-inflammatory agent is either or both of. . .pharmacologically active shark cartilage extract"" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

(iii) Claim 7 is vague and indefinite, as the metes and bounds are unascertainable. Since it is not know what the trademark Enzogenol is, what are equivalent bark extracts? The specification does not define this phrase and one of ordinary skill in the art would not be apprised of its meaning.

(iv) Claims 12, 26 and 27 are vague and indefinite, as they are confusing. Are "compounds providing a pharmacologically acceptable form" part of the "one or more of the following components" Markush group? It is not clear whether this clear recites two independent Markush groups or if the "compounds" are part of the Markush "components" group.

(v) The phrases "to be suitable for addressing" and "The method for addressing" in claims 15, 18, 32-34 is vague and indefinite, as its metes and bounds are unascertainable. What does it mean to address these disorders in a suitable way? Does it mean to treat them? The specification does not define this phrase and one of ordinary skill in the art would not be apprised of its meaning.

(vi) The Markush group in claim 16 is vague and indefinite, as it is confusing. Why is there an "or" between "bolus" and "tablet", but commas between the rest of the members of the Markush group?

(vii) The phrase "degenerative joint complaints, other cartilaginous degeneration" in claim 22 (lines 2-3) is vague and indefinite, as it is confusing. Does Applicant intend to treat a complaint or is Applicant treating the degenerative joint? What other cartilaginous degeneration? There is no cartilaginous degeneration mentioned in the claim prior to the above phrase.

(viii) The Markush language of claim 22 is vague and indefinite, as the metes and bounds of the claim are unascertainable. What composition is being administered? Is it a composition comprising two of GLME, a pharmacologically active green lipped mussel product, shark cartilage, pharmacologically active shark cartilage extract, or bark extract? Or is it a composition comprising two of GLME, a pharmacologically active green lipped mussel product, shark cartilage, or pharmacologically active shark cartilage extract, and a bark extract. For the purposes of examination, the Examiner has interpreted them in the first description.

(ix) The Markush language in claims 1-2, 14, 30-31 is vague and indefinite, as it is confusing. Why is there an "and/or" between the first two members, and an "and" between the second and third member?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croft (GB 2347349) in view of Dupont et al. (6,028,118).

The instant invention is directed toward a composition comprising at least on anti-inflammatory agent selected from green-lipped mussel extract or shark cartilage, and at least one enhancing agent selected from a bark product, a bark extract, or shark cartilage, wherein for a composition including just one member from each group, the selected members must be different.

Croft teaches a synergistic composition comprising green-lipped mussel extract and glycosaminoglycan for treating osteoarthritis or rheumatoid arthritis. The glycosaminoglycan can be in the form of chondroitin sulphate. The composition may be administered in capsule or tablet form, i.e., oral administration. Taught is a method of treating inflammation in a non-human animal. The reference lacks an enhancing agent. See abstract; pages 2-4; 7-8.

Dupont et al. teach a method of treating arthritis by administering an extract of shark cartilage. The shark cartilage is taught as having anti-angiogenic and anti-inflammatory activities. See Col. 28, lines 48-56.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the shark cartilage extract of Dupont et al. to the composition of Croft because it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. In re Kerkoven, 205 USPQ 1069 (CCPA 1980). Additionally, it would have been obvious to add the

shark cartilage extract of Dupont et al. to the composition of Croft because of the expectation of enhancing blood flow to the suffering area.

Claims 12, 26, 27, 29, 30, are rejected under 35 U.S.C. 103(a) as being unpatentable over Croft in view of Dupont et al. as applied to claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 above, and further in view of Henderson et al. (6,255,295).

Croft and Dupont are applied as discussed above. The references lack preferred additional pharmaceutically active agents.

Henderson et al. teach compositions for the treatment, protection, repair, and reduction of inflammation of connective tissue for conditions such as arthritis. Chondroitin sulfate is taught for use in combination with glucosamine for the treatment of osteoarthritis. The compound inhibits the degradative enzymes that break down connective tissue, thereby promoting the maintenance of healthy connective tissue. Vitamins B12 and B6, folic acid, dimethylglycine, trimethylglycine, and others are taught as ingredients that augment the function of S-adenosymethionine, which promotes the production of connective tissue matrix, and are taught as likely to be lacking in patients suffering from connective tissue disorders. It is taught that compositions that treat inflammation of connective tissue can be administered to humans or animals. See abstract; Col. 3, line 58-Col. 4, line 12; Col. 6, lines 44-56.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add vitamin B12, as taught by Henderson, to the composition of the combined references because of the expectation of promoting the production of connective tissue matrix.

Claims 9, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croft in view of Dupont et al. as applied to claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 above, and further in view of Church (Velvet Antler: It's Historical Medical Use).

Croft and Dupont et al. are applied as discussed above. The references lack deer velvet.

Church teaches that in 1996, researchers at the University of Alberta demonstrated that glycosaminoglycans in the water soluble fractions of velvet antlers have growth promoting effects on cells, and anti-inflammatory properties. See "Review of Scientific Literature on Elk Velvet Antler".

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add deer velvet, as taught by Fisher et al., to the composition of the combined references because of the expectation of achieving a composition that further combats the inflammatory response, thereby easing arthritis.

Claims 7, 8, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croft in view of Dupont et al. as applied to claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 above, and further in view of Burger (5,843,919).

Croft and Dupont et al. are applied as discussed above. The references lack anti-oxidants.

Burger teaches that vitamin E can to be added to compositions comprising glucoaminoglycan that treat arthritis, as additional components. See abstract; col. 4, lines 22-34.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add vitamin E, as taught by Burger, into the composition of the combined

references because of the expectation of achieving cells that are protected against free-radical damage and hence, are healthier.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Croft in view of Dupont et al. as applied to claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 above, and further in view of Kosuge et al. (4,801,453).

Croft and Dupont et al. are applied as discussed above. The references lack an effective amount for to provide gastro-intestinal protection.

Kosuge et al. teach compositions comprising green-lipped mussel extract for treating arthritis and gastro-intestinal irritation, conditions, lesions, and/or ulcer formation. See abstract; Col. 1, line 62-Col. 2, line 48.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of the combined references in an amount effective to provide gastro-intestinal protection because Kosuge et al. teach that compositions comprising green-lipped mussel extracts can be formulated to treat gastro-intestinal disorders or arthritis; thus, one of skill in the art would be motivated to teach an amount effective to provide gastro-intestinal protection because of the expectation of achieving a method of treating gastro-intestinal disorders.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
June 27, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

6/27/03